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Nanoscience and nanotechnologies: hopes and concerns

A legal version of the nanoworld ☆

La version juridique du nanomonde

Stéphanie Lacour

Team "Normativities and new technologies", CECOJI (UMR 6224 CNRS-Poitiers Université), 27, rue Paul Bert, 94204 Ivry sur Seine, France

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ABSTRACT

Nanosciences and nanotechnologies come into a pre-existing legal system. Their arrival, and how they are received are worthy of analysis. Such an effort shall at first include simply lexical considerations, in order to penetrate, via their origins, the traces of these specific objects into the territory of law. The goal of this article is to explore the effects of "nanos" in various legal fields, including their relevance to the principle of precaution, patent law, and the applicable laws for chemical substances.

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R É S U M É

Les nanosciences et nanotechnologies viennent s'inscrire dans un système juridique préexistant. Les modalités de leur réception par le droit méritent d'être analysées. Pour mener à bien cet exercice, il convient, après avoir exclu la piste d'une recherche purement lexicale, d'explorer quelques-unes des traces que l'émergence de ces objets spécifiques laisse dans le territoire du droit. C'est ce que tente de faire cet article, en se penchant sur l'effet des « nanos » dans différents champs juridiques, allant du principe de précaution jusqu'au droit des brevets d'invention en passant par le droit applicable aux substances chimiques.

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1. Introduction

Science and Technology have been imagined, encouraged, and conceived by and for Society as a whole. All such activities must logically be integrated within the existing normalized frameworks,¹ as far as applicable. However, the existing legal framework must be re-evaluated in view of any new aspects which are specific to new objects, new activities, and/or any new applications.

Nanosciences and Nanotechnologies (N&N) of course must obey this basic rule, even more so in that the more or less arbitrary² grouping of N&N according to a mere physical dimension (i.e. the order of nanometers) considerably broadens the scope of the rules of law which are or become pertinent and applicable.

☆ Translation from French on the basis of a project by Bradford Smith, Member of the New York Academy of Science, of the International Institute of Space Law, European Patent Attorney and Member, of the Chartered Institute of Linguists.

E-mail address: lacour@ivry.cnrs.fr.

¹ By normalized framework we mean all of the different standards (legal, ethical, technical, and also economical) which exist in a given society.

² Of course the scale is not at all arbitrary within the metric system, but the choice of this parameter to group together a set of scientific and technical research has been principally guided by science and technology policy, as is witnessed by the difficulties encountered in the normalization point of view, within the definition of this field. Cf. the standard DD CEN ISO/TS 27687:2009.

As N&N are by nature transversal, interdisciplinary and innovating, they are also potentially present in all industrial sectors, thus the emergence of N&N shakes up the established players in each stage of the life cycle of N&N, in terms of their practices in research and development, as well as in the ways of interacting together, such as mutual information exchange, throughout the phases of manufacturing and consumption of goods.

Among other normative regimes, the role of the law is to take account of these questions, as well as the accompanying social rules such as ethics, deontology, technical standards, or any other more or less structured standards.

Interpretation in case law shall follow, offering a uniquely privileged point of view upon the evolution of Society itself, which confers legitimacy to the evolving applicable legal and social standards. So then what can be said about law in the nanoworld?

2. Nano law? Misleading clues and the chosen method

What if, as pointed out by Marie-Angele Hermitte,³ *“the Spirit of Law remodels the reality supplied at input, by forcing objects from other worlds to fit into the logic of its categories and associated topographies.”* How is this world interpreted within our French and European legal system?

In order to examine and choose among many possible replies to such a question, first we suggest eliminating any research dealing with purely semantic questions. Some paths lead to dead ends, which is without a doubt the case of the former French proposal to create a specific legal regime for nanoparticles and nanomaterials discussed in Section 2.1. Other paths worthy of further investigation include taking into account the challenges represented by N&N in a legal context in order to analyze the replies offered (discussed under 2.2).

2.1. “Unknown at this address”⁴

Do we find any legal texts dedicated to our specific field of objects, science, technologies of N&N? Until recently, the answer was NO.

In French law, this has changed since the first “Grenelle” laws,⁵ which specifically mentioned N&N twice, with an obligation to declare any substance in “a nanoparticle state”⁶ This law consecrates “nano” as a legal term.

However, does the creation of this new legal term reflect in itself N&N as redefined in applicable law? Of course not. It is both impossible to assert that these legal articles constitute the applicable law in N&N and absurd to pretend that N&N escaped any and all legal dispositions before the existence of these new legal dispositions.

It becomes obvious from these first specifically applicable articles of law how awkward it is for the public power to apprehend “nano” objects. Confronted with the limits of a vocabulary which has been widely used within the framework of their public policies in science and technology, especially in funding of such; the tendency has been to consecrate the use of “neologisms”. These obscure vocabularies for non-experts, add an additional layer of linguistic complexity, as well as leading to an additional and unfortunate lack of legal certainty.

Finally, the most visible event in French law⁷ has been the creation of a totally new category of nanoparticle substances, whose exact nature remains to be defined.

The current result is that the legal existence, and/or legal significance of N&N is fleeting and floating, piecemeal and fragmented. That is an understatement. Furthermore, their political existence has not by any means been clarified.

A first intermediate conclusion is that the legislator has indeed created a new legal concept, an object whose indeterminate boundaries and content cover only a very limited portion of the N&N constellation of potential problems.

Although there is apparent will and effort to have as broad a reply as possible to the specific question of the potential impact of nanoparticles upon health and the environment, the legislator has from the outset been limited in action by the first premises of the procedure underlying the action.

In particular, the Requirement issued from the Grenelle environmental conference⁸ to *“prevent or anticipate, in the manner of an expert evaluation, with intelligence gathering and vigilance with respect to the risks related to products, techniques, and modifi-*

³ Marie Angele Hermitte, “Le droit est un autre monde”, Enquête, les objets du droit, 1999. May be found at <http://enquete.revues.org/document1553.html>, consulted on 7 October 2010.

⁴ We have borrowed the subtitles of the different parts of this paper from the following authors, who are cordially thanked in advance: Kressmann Taylor, Jonathan Franzen, Didier Van Cauwelaert, Michel Houellebecq and Pierre Jourde.

⁵ Respectively French laws no. 2009-967 of 3 Aug. 2009 on the programming relative to the implementation of the Grenelle environmental law, and law no. 2010-788 of 12 July 2010 on the national engagement in favor of the environment.

⁶ Substances in a nanoparticle state are mentioned in the article of the “programmation” law and in article 185 of the law for the national engagement in favor of the environment.

⁷ Concerning the idea that the normative register of N&N is indeed present, but sometimes less visible, see “La régulation des nanotechnologies. Clair-obscur normatif” under the direction of S. Lacour, published by Editions Larcier, 2010.

⁸ Procedure launched on 6 July 2007, bringing together governmental and civil representatives to define a roadmap in favor of ecology and sustainable development. Six working groups were formed with representatives from five colleges who were to represent all actors of sustainable development: representatives of non-governmental organisations and of French government, employers and employees, and territorial collectivities.

cations to the environment while accompanying innovation”,⁹ was the result of debates organized between the interested actors in the above mentioned conference.

This first Grenelle requirement was associated with the expression of the need for a regulatory framework concerning the evaluation and regulation of products incorporating nanomaterials, and the creation of a consultative body representing the different working groups of the Grenelle conference to follow-up of the various actions adopted with regards to nanotechnologies.

A careful reading of the documents published in the following stages of the Grenelle conference leading up to the vote of the two laws¹⁰ allows the attentive reader to appreciate the evolution of the initial postulates. In particular, public participation in the decision process was greatly modified, as was the evolution of the requested regulatory framework. At first foreseen only concerning nanomaterials, evolved to nanoparticles and nanomaterials, then finally “*substance(s) in a state comprising nanoparticles, whether alone or contained in mixtures in which they are not bound, or materials which may release such substances under normal conditions or reasonably predictable conditions of use*” was voted on in the law of July 2010.

Still, even after the legislative texts resulting from such a procedure, it is difficult to pretend that all within the vast fields potentially concerned by N&N is satisfactorily regulated.

2.2. “The uncomfortable zone”: Reflections on a framework in construction

Yes, in fact, the extent of fields potentially included in N&N is enormous, depending on the definition. The concept of N&N has been built up in the 1990’s by scientists and politicians in a manner which englobes whatever is convenient for political or funding purposes.

N&N has become a password,¹¹ allowing scientists and politicians to reorient their priorities in science and technology, but leaving the future open for adjustments of the definitions.

We do have a sort of definition from the EC 2004¹² along with the contextual elements which are put forth in the first paragraph(s) of the action plan¹³ published in 2005, confirming this observation.

In view of such a variety of scientific and technological activities, and the diversity of possible applications, it seems at first view that several fields of law are potentially concerned with the emerging N&N, including but not limited to: laws concerning public or private research, patent law, laws in the workplace, environmental law, tax law, forum shopping, and commercial law, in particular as it concerns end users (or consumers). We also observe that European Community law contributes to a multitude of legislations which go beyond and mix different disciplines and branches of law. For example, cosmetics, pharmacy, foodstuffs, and different chemical substances, biotechnologies, etc. are all equally concerned by nanotech applications.¹⁴ On the European level, it is in fact the different sectorial legislations which were the first to address the specific nature of N&N.¹⁵

Thus in order to understand and evaluate the relevant legal translation of the N&N world, we must investigate not only numerous texts, but also different branches of law and various legal disciplines. To undertake such a program, even if non-exhaustive and obviously incomplete, one needs a clearly defined *motus operandi*. A few different methods come to mind.

One method which is successfully used within the project NanoNorma,¹⁶ follows the analysis of the legal dispositions available “from cradle to grave”, throughout the life cycle of nanoproducts. Starting in a research lab, then finally ending up in the environment, sometimes as waste products, this project attempts to address each step in the cycle and also covers the relevant legal framework applicable to each.

In the present article we take a different approach, in which we bring together the different legal instruments available according to the effects which the emerging N&N have on their application in this new field.

⁹ The working group no. 3, entitled “Creating a health-friendly environment”, submitted its report on 27 Sept. 2007.

¹⁰ Summaries of working groups, general round tables, preparation of drafts of laws, Parliamentary work, etc.

¹¹ The vagueness of the word has been denounced many times throughout the debates organized by the French National Commission on Public Debates (CNDP) during winter 2009–2010, as witnessed by the minutes of the debates published by the Commission Particulière du débat public which organised them. Cf. esp. p. 24 of the minutes which may be found at: <http://debatpublic-nano.org/informer/bilandeabat.html>. For a sociological and political analysis of the use of this term, cf. Laurent, V. Brice (2010), “Les politiques des nanotechnologies, Pour un traitement démocratique d’une science émergente”, Editions Charles Léopold Mayer, Sept. 2010, esp. p. 26 and following.

¹² Communication COM(2004) 338: “Towards a European Strategy in favor of nanotechnologies”.

¹³ Communication “Nanosciences and Nanotechnologies: an action plan for Europe 2005–2009” COM (2005) 243: “Nanosciences and nanotechnologies (N&N) are new approaches to research and development (R&D) that concern the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale. Advances across a wide range of sectors are being enabled through R&D and innovation in N&N. These advances can address the needs of citizens and contribute to the Union’s competitiveness and sustainable development objectives and many of its policies including public health, employment and occupational safety and health, information society, energy, transport, security and space.”

¹⁴ For developments illustrating this effect of community law, in the particular case of consumer protection, cf. in French: Sylvie Pugnet, « La réglementation de la sécurité des produits : un risque pour l’entreprise », Contrats Concurrence Consommation n° 10, oct. 2009, étude 10. Cf. also Spinosoi, C.J. (2002) : “La structure du droit français,” RIDC 2002, v. 54, No. 2, esp. p. 271.

¹⁵ Cf. Regulation (CE) no. 1223/2009 of 30 Nov. relating to cosmetic products.

¹⁶ This study is currently underway within the framework of the project NanoNorma “From innovation to use: which normative framework for nano-objects?”: (<http://www.nanonorma.org/>), funded by the French National Agency for Research in the chapter National Program for Nanosciences and Nanotechnologies (No. ANR-08-NANO-001-01).

3. The reception of “nanos” by the law: Chosen effects

From such a point of view, we see that according to the different scientific or technology field concerned, the effects in the legal world shall react on a scale which varies from retouching pre-existing questions and corresponding texts to a profound total questioning of the principles and methods employed, which can lead to confusion even in recently updated fields of law. We submit that in spite of overlapping effects, or totally distinct effects without interaction, that we are still able to give at least an approximate overview of some perceptible variations in the manner with which some N&N will be considered within our existing legal framework/structure.

3.1. “Foreign Body”¹⁷: Branches of law in situations of uncertainty

In fact, existing law is not ignorant of the uncertainty problems.¹⁸ We even have a recent amendment¹⁹ to the French Constitution named the precautionary principle, which specifically addresses unspecified risks. Such considerations were not lacking in the French legal system before the Environmental Charter of Grenelle which cites an earlier “Loi Barnier”, 1995 (cf. Art. L. 110), and EC law which has elevated precaution to status of a general principle of EC law. Such considerations, expressed via an international environmental law²⁰ were quite naturally extended to sanitary risks,²¹ even though the existence of such a text and conditions of putting it into practice remain under critical discussion.²²

Of course the “principle of precaution” remains the fundamental text in the field of N&N, particularly for liability and risks of damages related to manufacture, use, etc. of nanoparticles and nanomaterials. Public authorities have not brushed this aside, and numerous communications²³ and recommendations²⁴ as well as opinions emanating from agencies or expert committees²⁵ are dedicated to the development of N&N in Europe since 2004.

As the principle of precaution implies the installation and use of methods of risk evaluation and mitigation, in addition to the adoption of temporary measures proportional to said risks in order to avoid a potential threat or damages, also push for financial support of research into risks associated with nanomaterials to health and the environment.

We remind the reader only in passing of the difficulty of concrete application of such lofty principles. The reader is referred to the written records of the public debates,²⁶ concerning the development and the regulation of nanotechnologies, organized by the CNDP (Commission nationale du débat public) between October 2009 and February 2010 under the auspices of the French Government.

In French law, the principle of precaution has extended its field of application concerning N&N. It encompasses the activities of public authorities, including their activities as employers, thus intruding into the sphere of influence of law of the workplace, and is particularly strict concerning HSE (Health, Safety and Environment) issues. Conceived at the outset to take account of the uncertainty of risk of damages, the principle of precaution was naturally brought by the defenders of health in the workplace. Workers in N&N are exposed by their employers to potential consequences of their activities in contact with nanoparticles or nanomaterials. What protective measures should be put into place by the employers?

Such a question is all the more vital in that the health risks for employees in contact with N&N are very uncertain at this point in time, even if new data is being constantly accumulated.²⁷

¹⁷ As a form of homage, our chapter titles are borrowed from Kressmann Taylor, Jonathan Franzen, Didier van Cauwelaert, Michel Houellebecq, and Pierre Jourde. Our thanks to the authors.

¹⁸ Cf. in French: S. Desmoulin-Canselier and S. Lacour, «Le droit à l'épreuve des nanotechnologies (ou les nanotechnologies à l'épreuve du droit)», Les Nanosciences. 4. «Nanotoxicologie et nano-éthique» directed by M. Lahmani, F. Marano, and Ph. Houdy, Editions Belin, 2010.

¹⁹ In application of the article 5 of the Charter for the environment promulgated on 1 March 2005 and introduced into the preamble of the constitution of 1958, “when damage is realized to potentially affect the environment in a serious and irreversible manner, even if uncertain within the state of scientific knowledge, the public authorities oversee, by the application of the principle of precaution within their fields of attribution, the implementation of procedures for evaluation of risks and the adoption of temporary measures proportional to the perceived risks in order to prevent the damage from occurring”.

²⁰ See the decisions: TPICE, 26 November 2002, affair Artegaodan: T-74/00, point 184; TPICE, 11 September 2002, affair Alapharma: T-70/99, point 171.

²¹ Cf. Ch. Noiville, «Science, décision, action : trois remarques à propos du principe de précaution», Petites Affiches, 1^{er}-2 novembre 2004, n° 218–219, p. 10.

²² Among the most well known are perhaps those of François Ewald, founder of the Observatory of the Principle of Precaution, and of Maurice Tubiana, member of the French Academy of Sciences. See also, F. Ewald, «Le principe de précaution oblige à exagérer la menace», Le Monde, 9 janvier 2010 or again M. Tubiana, in «Le principe de précaution : bilan de son application quatre ans après sa constitutionnalisation», Minutes of the public audition of 1st October 2009 organised by the French OPECST (Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques).

²³ Cf. in particular the European Commission Communication «Reglementary Aspects of nanomaterials», COM (2008) 366.

²⁴ Recommendation 2008/345/CE of the European Commission concerning best practices for responsible research in nanosciences and nanotechnologies of 7 February 2008.

²⁵ In France, the Committee for the Prevention and Precaution was the first to be questioned on N&N, cf. the Opinion of the Committee for the Prevention and Precaution, Ministry of Ecology and Sustainable Development, May 2006, “Nanotechnologies, nanoparticles, which dangers, which risks?”. This first text was followed by several other opinions and recommendations, among which those of the AFSSET (Agence Française de Sécurité Sanitaire de l'Environnement et du Travail) in 2006, 2008 and 2010.

²⁶ The notes of the actors and the minutes of the debates, as well as the conclusions published by the Commission Particulière de the Public Debate may still be available on-line at the following address: <http://www.debatpublic-nano.org>.

²⁷ We refer the interested reader to the article of Eric Gaffet in this volume for further development of this subject.

In such an environment, application of the principle of precaution goes beyond its initial goal, which was conceived as a simple, additional protection extending to unknown risks, but now appears to be most pertinent and perhaps of utmost importance for workplace risks.

Whether in the workplace, public health, or environmental fields, the hypothesis may be put forth for the treatment of such questions arising from nanoparticles or nanomaterials.

In a first hypothesis, the risks associated with the products are known or at least the risks probabilities lend themselves to reasonable conjecture. For example, insurance might work. In such a scenario, simple prevention according to normal workplace law applies and should be sufficient.

However, in the second hypothesis, infinitely more likely in the current state of scientific knowledge of nanomaterials, the risks are largely unknown, thus the principle of precaution is the preferred reference.

A perceptible interpretation as above is noticeable in various position statements concerning nanomaterials in the workplace. In 2009, the French MEDEF²⁸ issued a statement²⁹: “enterprises wishing to innovate using nanotechnologies should take appropriate preventative measures and precautions which take into account the level of uncertainty of our current knowledge”.

In fact, the MEDEF explicitly took the position of the Committee of Prevention and Precaution in 2006, which stated: “In the case that toxicology measurements cannot establish tolerable limits of exposition to a product, the principle ALARA (As Low As Reasonably Allowable) should be applied”.

The ALARA takes into account that the workers should be protected “without waiting for proof of toxicity or not of different nanoparticles”. But also with a proportional character for putting such precautionary measures into effect.

However, this interpretation in French practice comes up against the general principle for workplace hazards. In France, the Code du Travail says that “the employer takes the necessary measures to ensure the security and to protect the physical and mental health of workers. These measures include: (1) actions to prevent professional risks; (2) actions of information and training; and (3) the installation of adapted organization and means. The employer watches over the adaptation of these measures in order to take into account evolving circumstances as well as to improve existing situations.” This employers’ obligation has been interpreted since 2002 in case law concerning asbestos as an obligation of result.³⁰

So what is the situation in the presence of a risk which the employer might be aware of as a possibility, but which in the current state of scientific knowledge is still uncertain? This type of risk is known to exist in the field of N&N. Is the mere probability of an uncertain risk perhaps enough to engage the employers’ responsibility?

If a negative reply to this question is put forth in the fields of civil liability or administrative liability, should this negative reply have any repercussion on the extent of the measures of prevention which the employer is required to put into place in the workplace, and in particular the mention of a potential risk within the only specific document foreseen by the articles R.4121 and following of the Code du Travail?

In case of fact, is uncertainty a sufficient condition to exclude the application of the principle of prevention? Or should this uncertainty lead to even more strict measures of the workplace law, wherein the employer is also required to have an increasing responsibility of ongoing surveillance of the evolution of the scientific state of knowledge? Such a solution has been put forth in the work of the AFSSET in 2008,³¹ as well those of the Haut Conseil pour la Santé Publique in 2009.³² Some recent case law interpretations³³ of the principle of precaution have gone in this direction, that the employees can reasonably invoke legitimate fears, even in the absence of any scientifically established relation of cause and effect, that such products may provoke effects which allow them to cease working.³⁴

Where should we place the pointer in the interpretation of a principle imported from a different branch of law? We can easily see from this example that the exercise is perilous. The interpretation given to the principle of precaution in the field where it originated may lead to contrasting results, having for effect reduced protection of worker safety and health, or on the contrary, reinforcement to such a degree that any N&N commercial activities would become illusory.

²⁸ “Mouvement Des Entreprises de France”. Organization bringing together the Directors of the main French enterprises.

²⁹ <http://www.debatpublic-nano.org>.

³⁰ Soc., 28 février 2002, pourvois n° 00-13.172, n° 99-18.389, n° 99-17.201 : « En vertu du contrat de travail le liant à son salarié, l'employeur est tenu envers celui-ci d'une obligation de sécurité de résultat, notamment en ce qui concerne les maladies professionnelles contractées par ce salarié du fait des produits fabriqués ou utilisés par l'entreprise ; le manquement à cette obligation a le caractère d'une faute inexcusable, au sens de l'article L.452-1 du Code de la sécurité sociale, lorsque l'employeur avait ou aurait dû avoir conscience du danger auquel était exposé le salarié, et qu'il n'a pas pris les mesures nécessaires pour l'en préserver ». Roughly translated as follows: “by virtue of the contract binding him with the employee, the employer is obligated by the security of the result to his employee, in particular as concerns professional illnesses which are the result of the employee being exposed to products manufactured or used by the enterprise; if this mandatory result is not obtained, it is a non-excusable fault of the employer, within the meaning of article L. 452-1 of the Code of Social Security, insofar as the employer had or should have had awareness of the danger to which the employer was exposed, and the employer did not take the necessary measures to protect his employee from said danger”.

³¹ AFSSET, Opinion on « Nanomatériaux et sécurité au travail », July 2008, <http://www.afsset.fr/index.php?pageid=1686&parentid=229&ongletid=3929#content> (site consulted on 21 Octobre 2010).

³² Cf. Opinion of the Haut Conseil de la santé publique « la sécurité des travailleurs lors de l'exposition aux nanotubes de carbone » of 7 January 2009, at the following address: http://www.hcsp.fr/docspdf/avisrapports/hcspa20090107_ExpNanoCarbone.pdf.

³³ Cf. Cour d'Appel de Versailles, 14^{ème} ch., 4 February 2009, and commentary of Ph. Stoffel-Munck, « La théorie des troubles du voisinage à l'épreuve du principe de précaution : observations sur le cas des antennes relais », or “the theory of good neighbor policy challenged by the principle of precaution: observations on the case of relay antennas” D. 2009, n° 42, chron. p. 2917, among others.

³⁴ Article L. 4131 of the Code du Travail.

A similar analysis could be undertaken in other legal fields concerned with N&N, for example insurances, whose main concerns are the uncertainty of the risks associated with N&N activities, which pushes insurers to develop a *lege feranda* reading of liability law.

But this is not the only effect of these emerging technologies on the existing law. In other fields as well, the principles of application of legal texts are called into question, as witnessed by the recent skirmishes between the European Commission and Parliament concerning the question of risks related to nanotechnology.

3.2. “Elementary Particles” of best practices of risk management

In a certain number of fields including for example the regulation concerning chemical products, the legal standard may be evaluated both from the viewpoint of the principles as expressed and embodied, as well as the standards and technical documents which are necessary in order for putting them into practice.

Such standards and technical documents are expressly included in a “new” approach put forth since the mid 1980’s by the European Commission for the construction of the European Common Market.³⁵

In the matter of nanoparticles and nanomaterials, as put forth by Nathalie Hervé-Fournereau: “In contrast with a totalitarian coercive approach, the public authorities prefer to make use of a more instrumental approach which is both integrated and open to evolution, conjugating the use of voluntary approaches, adoption of recommendations, and guides of best practices and adaptation”,³⁶ rather than the elaboration of a specific legislation.

This approach has manifested itself since 2004, when the European Commission stated that in view of the fact that “Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, [...] documents that support implementation, particularly in relation to risk assessment, adopted within the context of current legislation will have to be reviewed in order to ensure that they effectively address risks associated with nanomaterials and make best use of the information becoming available.”³⁷

It thus seems possible, in light of the efforts of the European Commission, to assert that the elementary particles necessary from a legal point of view for risk management of nanomaterials are simply the technical documents which offer an explanation of the application of existing legislation, apparently without any need to investigate further the content of that existing legislation.

This interpretation of Community texts leads to a constant problem of a strong opposition from the European Parliament and its various commissions. “The European Parliament... does not agree, before an appropriate evaluation of current Community legislation, and in the absence of any nano-specific provisions therein, with the Commission’s conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks”.³⁸

The explanation of this contradiction in the interpretation of the text is found, in part, in the very heart of the pertinent regulatory disposition. This is the case in particular for the REACH³⁹ regulation, which seeks to establish a high level of protection for human health and environment while ensuring the free circulation of chemical substances within the Common Market, by regulating their fabrication, distribution and marketing, and their use. It is fair to point out that this regulation innovates through abolishing the long-established distinction between existing substances and new ones, such that all chemical substances are treated equally.

Another innovation is “This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.”⁴⁰

The limits of the regulation as concerns apprehension about nanoparticles and nanomaterials have been widely commented upon. According to Patrick Thieffry⁴¹ the most obvious is that the registry is mandatory in the text only for chemical substances which are fabricated or imported in quantities greater than one ton per year and per person (fabricant/importer).

³⁵ Politique de nouvelle approche entreprise en 1984 et objet d’une résolution du Conseil des communautés européennes en 1985 : Cons. CE, résolution 7 mai 1985 : JOCE n° C 136, 4 juin 1985, pp. 1–9.

³⁶ N. Hervé-Fournereau, La sécurité sanitaire et environnementale vis-à-vis des nanomatériaux, in: Dossier thématique «Droit et nanotechnologies», sous la direction de S. Lacour, Cahiers Droit, Sciences et Technologies n° 1, CNRS éditions, p. 57 et s.

³⁷ Communication from the European Commission to the European Parliament, the Council and the European Economic and Social Committee COM (2008) 366 final, Regulatory Aspects of nanomaterials. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:en:PDF>.

³⁸ European Parliament, Resolution of 24 April 2009 on the Regulatory aspects of nanomaterials. [http://www.europarl.europa.eu/RegData/seance_pleniere/textes_adoptes/definitif/2009/04-24/0328/P6_TA\(2009\)0328_EN.pdf](http://www.europarl.europa.eu/RegData/seance_pleniere/textes_adoptes/definitif/2009/04-24/0328/P6_TA(2009)0328_EN.pdf).

³⁹ Regulation (CE) n° 1907/2006, concerning registration, evaluation and authorization of chemical substances, and restrictions applicable to these substances (REACH). Cf. for example: E. Brosset, «Le règlement communautaire en matière de produits chimiques, petite explication de texte», RJE 1 (2008) 5.

⁴⁰ Article 1, §3 of regulation (CE) n° 1907/2006.

⁴¹ P. Thieffry, «La prise en compte du risque des nanoparticules et nanomatériaux. Information et réglementation en amont. Mise en perspective juridique» (“legal point of view on accounting for risks of nanoparticles and nanomaterials. Upstream regulation and information”) in «La régulation des nanotechnologies. Clair-obscur normatif», under the direction of S. Lacour, Editions Larcier, Paris, 2010, pp. 181–208.

Without going into further detail on the dispositions of the regulation (we refer the avid reader to other works⁴²), it is easy to take this first argument, often put forth to illustrate the problem of adapting the existing legislation to the specificities of nanoparticles and nanomaterials, to illustrate the difficulties which the legal system must confront in its apprehension of the nanoworld.

It is indeed sufficient to realize that the reglementary threshold of one ton per year and per operator (producer or importer) shall be difficult to reach on the European market for nanoparticles and nanomaterials, with maybe rare exceptions, and which may be easily circumvented by accounting tactics between actors in the sector. Only activities above the one ton threshold are of concern, according to a simple principle: the more the product is massively introduced in the marketplace, the greater the risks, and the details in the registry file depend on such considerations. In theory, greater risk in quantity requires better knowledge of those risks. On the other hand, the Commission feels that below a certain threshold, the obligation of registry would render the system impractical.⁴³ Such a statement, from our point of view, only hides the magnitude of modifications necessary to this text if one desires that it should correctly take account of the availability of nanoparticles and nanomaterials in the marketplace. In this case it is not because of the small quantities of fabrication or importation that the law has a problem to deal with them, it is because the units of measure used to determine the threshold of applicability are inappropriate. The effects of such products are related to the distribution of particle size or the materials of which they are composed, rather than their total mass, as pointed out by the experts of SCENIHR.⁴⁴

Simply lowering the threshold is not enough, a complete review of the implementation of the legislation is clearly necessary to take account of the relevant characteristics so that REACH has some sense with respect to nanomaterials.

It is quite evident that the text is not adapted by an overview of the technical documents necessary as a foundation for the practical implementation of the law. We observe that above a certain threshold, the entity is required to supply, along with its filing request, toxicology and eco-toxicology research and results, as far as known, plus a report on the chemical security.

These requirements seem irrelevant in relation to nanoparticles and nanomaterials in view of the lack of standardisation of technical means adapted to a risk evaluation for these products. This can be witnessed when observing the working groups of the OECD and ISO as they try to come to a consensus on technical parameters. There is a natural flow-on from the uncertainties in regards to technical parameters and their present and future evolution, to the legal texts which are based on the presumption of the founding principles.

This situation requires a deep and fundamental questioning of the established order which has been built on categories adapted to chemical substances, but which shall be brought into play in the new fields of nanomaterials and nanoparticles.

Behind the scenes, there are major interests (often hidden as usual) among the interested parties concerning the method employed to accompany the evolution of the standards framework, as well as the room allowed for the expression of diverging opinions. In this case, it's not only a concept imported from a different legislative branch which is in question, but the way in which the legal principles have been thought out (and not only their implementation) within a coherent legal framework.

Other sectorial legislations, in particular the authorizations for introducing a new medical product to market, give a perspective wherein N&N raises fundamental questions about the function of the legal system.

We shall conclude our rapid overview of the current legal translation of the nanoworld with the last hypothesis, concerning a deeper questioning of the legal modes chosen to reply to the questions formerly arising from the emerging technologies of the past.

3.3. "Lost Land" from patents to nanoelectronics

In two particular legal fields, N&N force the accent on questions which have arisen concerning former technologies, to such a point that the initial economy of these fields seems lost. We refer to law concerning personal data⁴⁵ and patent law.

In the first case, nanoelectronics allow the manufacture of powerful and reliable components at vanishing unit production costs. The economies of mass production allow the realization and implementation of object-based Internet, NFC⁴⁶ technology, and RFID⁴⁷ which will once again push the limits of the legal framework for the protection of personal data.⁴⁸

⁴² P. Thieffry, *ibid*, but also N. Hervé-Fournereau, « La sécurité sanitaire et environnementale vis-à-vis des nanomatériaux », *op. cit.*, or by the same author, « La régulation des nanotechnologies : des normes techniques aux normes tout court ou la nébuleuse normative », in: « La régulation des nanotechnologies. Clair-obscur normatif », under the direction of S. Lacour, *op. cit.* Editions Larcier, Paris, 2010, pp. 43–88.

⁴³ COM (2003) 644 final – Proposition for a regulation of the EP and Council concerning registration, évaluation and authorization of chemical substances, and restrictions applicable to these substances (REACH).

⁴⁴ Acronym for "Scientific Committee on Emerging and Newly Identified Health Risks". The European Commission has asked this committee of experts to formulate a scientific definition of nanomaterials in order to allow the drafting and implementation of a regulation. The work is still in progress at the time of this writing.

⁴⁵ Cf. for example, S. Lacour, « Ubiquitous computing et Droit. L'exemple de la radio-identification », in « La sécurité de l'individu numérisé », L'Harmattan, Paris, 2009.

⁴⁶ Acronym for Near Field Communication, a technique which allows information exchange without contact.

⁴⁷ Acronym for Radio Frequency IDentification, another technique which allows information exchange without contact.

⁴⁸ In France, the "loi Informatique et Liberté" (law n° 78-17 of January 6, 1978) concerning computing, data bases and liberties, attempts to take into account technological innovations and new computing uses and technologies. It has been modified 6 August 2004.

Our laws imply information, acceptance of the persons whose data are treated, and a well-defined purpose of those treatments. Such laws are not appropriate for invisible objects which are potentially everlasting.⁴⁹ While the attitude about traces left by individuals has evolved during preceding years, and has been addressed by many works, a more or less conscious behavior of persons is generally assumed, for instance for Internet users or biometry. In contrast, the features of objects made possible by nanoelectronics are such that communication may become independent of those who communicate. Objects are now communicating for us... and about us.

The CNIL, French commission created in 1978 by the “loi Informatique et Liberté”, reacted as early as 2003 by the publication of a remarkable communication.⁵⁰ Because of the danger of RFID concerning personal data protection, it recommends to treat RFID as data subject to the French law, implying that their deactivation should be easily possible. The various contributions of the CNIL⁵¹ to the public debate on nanotechnologies organized in France by the CNDP nevertheless show that its wish has not been completely fulfilled.

At the European level, the trend does not clearly favourable the general application of the legislation on personal data to electronic devices. The European Commission, though concerned with European competitive ability, clearly expressed in 2007,⁵² and even more in 2009,⁵³ the will to find for nanotechnologies “a legal framework that affords citizens effective safeguards for fundamental values, health, data protection and privacy”. Concerning this issue, as recalled by the “Article 29 Working Party”,⁵⁴ the legislation can only be adapted to new technologies at the cost of an intense reflection on the necessary interaction between law and technique. The law alone cannot solve the problems amplified by nanotechnologies. Nevertheless, a deep revision of the law is necessary. Unfortunately, the approach which has been suggested fails to take technological evolution into account correctly. An example is the recommendation made in 2009 by the European Commission who suggested co-regulation together with the Industry. If not correctly amended, the law may in the near future be deprived of any concrete effect.⁵⁵

The effect which N&N have in the field of patents is correlated to a number of factors which may be summarized as follows: most R&D in N&N is performed in academic⁵⁶ or institutional laboratories, this R&D is recent,⁵⁷ cutting edge, costly⁵⁸ and often interdisciplinary, it blurs the borders between science and technology, and last but not least, may have applications in numerous industrial sectors.⁵⁹ Each country hopes to recover its investment via patenting, in international competition which has become even more ferocious since these technologies promise to be the industrial revolution of the 21st century. The research community is thus solicited, as in the past in the fields of biotechnologies, to file patent applications as early as possible.⁶⁰ The patent offices, on the other hand, are confronted with an increasing flow of applications concerning objects which they have great difficulty to apprehend, and which are difficult to situate with respect to a state of the art. The latter is even less stabilized because even the vocabulary developed to name N&N products is in rapid evolution⁶¹ and calls upon knowledge from mixed and various disciplines.⁶²

The risks inherent in this context have been denounced early on, especially in the USA, and may be formalized via a concept already applied to the anomalies that were introduced to the patent system in the field of biotechnology: the tragedy of the lost commons.⁶³ It would seem in fact that numerous patents have been granted with claims too broad, and whose object does not always present the characteristics of a true patentable invention. The risk of such a situation is to

⁴⁹ RFID can operate without battery, as the energy is provided by the electromagnetic field of the reader.

⁵⁰ Communication of Philippe Lemoine on Radio-Identification (Radio-Tags or RFIDs).

⁵¹ The position of the CNIL is summarized in its “cahier d’acteur”, a booklet written by an ensemble of stakeholders expressing their views about a given topic (research institution, non-governmental institutions, trade unions, citizens).

⁵² Communication of the European Commission, *Radio Frequency Identification (RFID) in Europe: steps towards a policy framework* (http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0096en01.pdf).

⁵³ Commission Recommendation 2009/387/CE of May 12, 2009 on the implementation of privacy and data protection principles in applications supported by radio-frequency identification.

⁵⁴ The Article 29 Data Protection Working Party has been established by Article 29 of Directive 95/46/EC of the European Commission. Internet site http://ec.europa.eu/justice/policies/privacy/workinggroup/index_en.htm.

⁵⁵ The Article 29 Working Party has in July 2010 required to modify the proposal of the European industries in 2009. This testifies the problems to be solved to adapt the current rules in the case of a massive use of RFID. See opinion 5/2010 of July 13, 2010, Internet site http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2010/wp175_en.pdf.

⁵⁶ Cf. for example, OECD, Working Group on Nanotechnologies, “Nanotechnology: an overview based on indicators and statistics”, STI Working paper 2009/7, Statistical Analysis of Science, Technology and Industry.

⁵⁷ The earliest articles marked N&N appeared in the 1980’s, but it was only in the 1990’s that there was truly an explosion in the field.

⁵⁸ S. Lacour, « Le droit des brevets d’invention à l’épreuve des nanotechnologies », *Techniques de l’ingénieur*, janvier 2010.

⁵⁹ Cf. Angela Hullmann, The economic development of nanotechnologies – An indicators based analysis, p. 21 and following, November 2006. This article may be downloaded at <http://cordis.europa.eu/nanotechnology>.

⁶⁰ Cf. Masatura Igami, Teruo Okasaki, Capturing nanotechnology’s current state of development via analysis of patents, STI Working Paper, 2007/4, Statistical Analysis of Science, Technology and Industry, OECD.

⁶¹ Cf. Raj Bawa, Patents and nanomedicine, *Future Medicine*, Nanomedicine 2 (3) (2007) 351–374.

⁶² The United States Patent and Trademark Office (USPTO) created a new filing class number 977 for nanotechnologies in November of 2004. The European Patent Office (EPO) has created an internal classification for prior art examinations of submitted patent applications named Y01N.

⁶³ *The concept of the “tragedy of the anti commons”*. This concept has been modeled concerning the subject of patents in the field of biomedical research in 1998 by M.A. Heller, R.S. Eisenberg, *Can patents deter innovation? The anticommmons in biomedical research*, *Science* 280 (5364) (1 May 1998).

paralyse the innovation capacity of the entire community, which also inevitably will stifle the appearance in the marketplace of products issued from nanotechnologies.⁶⁴

This risk, already known to intellectual property specialists, is aggravated here by the fact that capital risk funding is hesitating to support R&D, leading to an increase of patent application filings, which are supposed to prove the viability of the technology to be chosen for exploitation.⁶⁵ The negative effects of this risk is again multiplied by the generic quality of the concerned technologies, which may further paralyze the corrective forces of the market place which have been observed and commented on in the framework of earlier technologies.⁶⁶

Patent thickets⁶⁷ and blocking patents⁶⁸ have been counterbalanced until now according to the applicable contractual strategies of different industrial sectors, with little regard to considerations of “social justice”. For example, in the field of electronics, we have seen the birth of patent pools⁶⁹ and cross-licensing arrangements. Although such arrangements may be criticized in particular with respect to competition law,⁷⁰ they do have the advantage to overcome the logjams created by too many blocking patents granted to too many parties concerning commercial products. In the pharmaceutical field, an opposite strategy is applied in a more classical application of the IPR, leading to buyout or liquidation of the weaker competitors under the threat of legal risks. Each industrial sector has developed its proper strategy: each is now confronted with an equally powerful strategy from other actors, giving rise to potential conflicts difficult to resolve. The increasing presence of institutional actors (universities or public research organizations) in this new game complicates the picture by adding to these economic difficulties the risk of seeing the undesirable effects of the perversion of the patent system quickly close off the flow of technology knowledge which may be useful for all.⁷¹

A patent law which is contrary to the promotion of invention, allowing profits to be gained by stifling invention and the sharing of knowledge is nonsense. It's still not too late to become aware of the drifting towards a misuse of patent law of which N&N are becoming a victim. Due to the specificities of N&N in such a context, we are confronted with an opportunity to reconsider the equilibrium between politics and policies of research and innovation which have gradually slipped away from the initial social functions which led to the elaboration of the legal regime.

4. Conclusion

The legal system may lose efficiency with respect to the upheavals introduced by N&N in relation to its proper frontiers, goals, and concepts. Such an evolution would be detrimental to an effective action concerning sanitary, social, and environmental effects of N&N, and by consequence, detrimental to the very development of N&N. It is indeed a major program to rethink our science and technology policies, our strategies, and our legal replies to questions raised by N&N.

In the end however, the field of law should be enriched and become more noble, at least more than it is at present, by the “unfortunate invention” of nanoparticle substances.

Appendix A. Supplementary material

The French version of this article is supplied as Supplementary Material with the electronic version of this article. Please visit [doi:10.1016/j.crhy.2011.06.007](https://doi.org/10.1016/j.crhy.2011.06.007).

⁶⁴ Cf. C. Shapiro, Navigating the patent thicket: Cross licences, patent pools and standard-setting, Conference on Innovation Policy and the Economy, p. 1, March 2001, but also in French language, Rémi Lallement, *Politique des brevets : l'enjeu central de la qualité, face à l'évolution des pratiques*, Horizons stratégiques, Revue trimestrielle du Centre d'analyse stratégique, n° 7, janvier–mars 2008.

⁶⁵ Annie Kahn, Les brevets sont devenus des armes sophistiquées de guerre commerciale, *Le Monde*, Paris, 26 février 2008. Translation: “Patents have become sophisticated arms of commercial war.”

⁶⁶ Cf. M. van Velzen, *IP in nanomedicine – perspective from an IP professional in industry*, *World Patent Information* 30 (2008) 294–299, 295.

⁶⁷ The image of patent thickets involves the hypothesis of a multitude of patents delivered for similar objects, overlapping partially one another, which is theoretically impossible.

⁶⁸ Another term well known to patent specialists, consisting of patent applications which are filed with broad claims, in the unique perspective to block the advancement of competitors on a specific market sector. Such patents are also theoretically outlawed but in practice, perfectly legal and frequently used.

⁶⁹ Patent pools are contractual mechanisms wherein the patent owners pool their patents into a common licensing scheme, which allows exploitation by the members of the pool of all the patents in the pool.

⁷⁰ Cf. for example F. Violet, Retour sur les embuscades tendues par les « patent trolls », *Propriété industrielle* 6 (juin 2010) 13 (Overview of the traps set by the patent trolls).

⁷¹ To such an extent that one may seriously ask oneself, in particular in the USA, if the universities are not acting as patent trolls. Cf. M.A. Lemley, Are universities patent trolls? Stanford Public Law Working Paper n° 980776.